REMARKS

Claims 27-28 and 31-47 are pending in the present application. Support for the amendment to the specification may be found, *inter alia*, on the same paragraph on page 10, lines 4-7, which cites the Application Serial No. of the patent from which U.S. Patent No. 6,610,718 issued. Claims 29 and 30 have been cancelled. Claims 27, 28, 31, 36, 37, 39, and 40 have been amended to more particularly point out the subject matter of the invention. Support for these amendments is found in the specification at page 9, lines 27-28. New claims 41 to 47 have been added. Support for the added claims 41-47 is found in the specification at page 9, lines 27-28. No new matter has been added. In view of the above amendment and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable. Reconsideration of the present application is requested.

Claims 27-28 and 31-39 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. patent No. 4,284,786 to Kammerer *et al.* ("the '786 patent"). Applicants respectfully traverse the rejection.

To anticipate a claim, a single reference must disclose the claimed invention with sufficient clarity to prove its existence in the prior art, and must disclose every element of the challenged claim. *Motorola Inc. v. Interdigital Technology Corp.*, 43 USPQ2d 1481, 1490 (Fed. Cir. 1997); *PPG Industries Inc. v. Guardian Industries Corp.*, 37 USPQ2d 1618, 1624 (Fed. Cir. 1996). Absence from the reference of any claimed element negates anticipation. *Kloster Speedsteel AB v. Crucible Inc.*, 231 USPQ 160 (Fed. Cir. 1986). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). An anticipatory reference must also enable one of ordinary skill in the art as to the claimed subject matter.

Claim 27, as amended, recites leflunomide containing about 150 ppm or less of N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide ("HCA").

The '786 patent discloses a process for the preparation of leflunomide by reacting 4-triflouromethylanaline ("TFMA") with a 5-methylisoxazole-4-carboxylic acid ("MIA") derivative. In the process, crude leflunomide is obtained by evaporation of the reaction solvent to dryness and subsequent crystallization in toluene. The '786 patent does not disclose the compound leflunomide containing about 150 ppm or less of HCA. Furthermore, the '786 patent does not enable the synthesis of leflunomide having about 150 ppm or less of HCA. In fact, the '786 patent is silent as to the impurities present in the leflunomide.

Applicants obtain leflunomide containing about 150 ppm or less of HCA through a different process than that disclosed in the '786 patent. Applicants' process involves using a weak base and obtaining leflunomide through a step-wise reaction scheme that reduces the level of HCA formed during the reaction.

Furthermore, the '786 patent does not enable the skilled artisan to synthesize leuflonomide having about 150 ppm or less of HCA, as required to anticipate claims to leflunomide containing about 150 ppm or less of HCA.

Therefore, because the '786 patent does not disclose leflunomide containing about 150 ppm or less of HCA or enable the skilled artisan to make the recited leflunomide, the '786 patent cannot anticipate the claims. For the reasons discussed above, the '786 patent does not anticipate claims 28 and 31-39, which depend from claim 27. Because the rejection cannot stand, withdrawal of the rejection is respectfully requested.

Claims 27-28 and 31-40 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. patent No. 6,060,494 to Faasch *et al.* ("the '494 patent"). Applicants respectfully traverse.

Claim 27, as amended, recites leflunomide containing about 150 ppm or less of HCA.

The '494 patent discloses a polymorph of leflunomide, referred to as the "first crystal modification," and a process for preparing the polymorph. Lefluonomide is made according the '786 patent. The '494 patent, col. 2, ll. 23-25. The first modification is obtained by heating a suspension of crystals in a solvent to a temperature of about 10°C to about 40°C. *Id.* col. 3, ll. 1-5. The process uses solvents in which leflunomide is poorly soluble. *Id.* at ll. 7-9. A second method comprises dissolving leflunomide or a second crystal modification thereof or mixtures of the first and second modifications the cooling the solution abruptly to temperatures from -5°C to about -25°C. *Id.* at ll. 25-30.

The '494 patent fails to anticipate the recited claim, because the '494 patent fails to recite each and every element of the claim. The '494 patent is silent as to the purity of the leflunomide obtained. As explained above, the process of the '786 patent does not produce leflunomide containing 150 ppm or less of HCA. This is the starting material used in the '494 patent. Consequently, the leflunomide disclosed in the '494 patent , being prepared from this method, cannot contain 150 ppm or less of HCA.

Therefore, the '494 patent does not anticipate claim 27, as amended, because the '494 patent does not disclose leflunomide containing about 150 ppm or less of HCA, and does not enable one to obtain leflunomide containing about 150 ppm or less of HCA.

Because the '494 patent does not disclose or enable one skilled in the art to obtain leflunomide containing about 150 ppm or less of HCA, the reference does not anticipate claims 28 and 31-40, which depend from claim 27. Therefore, withdrawal of the rejection of claims 27-28 and 31-40 is respectfully requested.

It is believed that this application is in condition for allowance and applicant respectfully requests such action. If any outstanding issues remain, the examiner is invited to telephone the undersigned at the telephone number indicated below to discuss the same. No fee is believed to be due for the submission of this response. Should any fees be required, please charge such fees to Kenyon & Kenyon, LLP Deposit Account No. 11-0600.

Respectfully submitted,

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